



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0941; FRL-9906-19]

Fluopicolide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for indirect or inadvertent residues of fluopicolide in or on corn, field, forage; corn, field, grain; corn, field, stover. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0941, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0941 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0941, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (2F8099) by Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200; Walnut Creek, CA 94596. The petition requested that 40 CFR 180.627 be amended by establishing tolerances for indirect or inadvertent residues of the fungicide fluopicolide, 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]-benzamide, and its metabolite, 2,6-dichlorobenzamide, in or on corn, field, forage at 0.09 parts per million (ppm); corn, field, grain at 0.01 ppm; and corn, field, stover at 0.3 ppm. These tolerances are being requested for fluopicolide residues that are likely to be found in or on corn when corn is planted as a rotational crop into a field that has previously been treated with fluopicolide, not for residues that result from direct application of fluopicolide to corn. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which EPA failed to make available through <http://www.regulations.gov>. Subsequently, EPA posted the summary to the docket via <http://www.regulations.gov> and republished notice of the availability of Valent's summary of its petition in the docket on September 12, 2013 (78 FR 56185) (FRL-9399-7). There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances for corn, field, forage from 0.09 ppm to 0.08 ppm; and for corn, field, stover from 0.3 ppm to 0.20 ppm. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopicolide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopicolide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicological database indicates that fluopicolide has relatively low acute toxicity. Fluopicolide is not a dermal sensitizer, primary eye irritant, or primary skin irritant. The subchronic and chronic toxicity studies showed that the primary effects of fluopicolide are in the liver. Kidney and thyroid toxicity were observed in rats only. Fluopicolide is not neurotoxic, carcinogenic, nor mutagenic. Developmental toxicity in the rabbit occurred only at doses that caused severe maternal toxicity (including death). In the rat, developmental effects were seen only at high dose levels (700 milligrams/kilogram/day (mg/kg/day)) in the presence of maternal toxicity. Similarly, offspring effects (decreased body weight and body weight gain) occurred only at levels causing significant toxicity in parents of the multi-generation reproductive toxicity study. There is no evidence of increased quantitative susceptibility of rat or rabbit fetuses to *in utero* or postnatal exposure to fluopicolide. No toxic effects were observed in studies in which fluopicolide was administered by the dermal routes of exposure. The toxicological profile for fluopicolide suggests that increased durations of exposure do not significantly increase the severity of observed effects. The rabbit developmental and rat chronic/cancer studies were therefore considered as potential studies for deriving risk assessment

endpoints for all durations of exposure. Fluopicolide is classified as “not likely to be carcinogenic to humans”, thus no quantification of cancer risks is required.

Fluopicolide shares a metabolite, 2,6- dichlorobenzamide (BAM), with another active ingredient, dichlobenil. Residues of BAM are considered to be of regulatory concern, and separate toxicity data and endpoints for risk assessment have been selected for BAM. Since the toxicity profile for BAM has not changed since the last assessment EPA conducted for BAM, an analysis of the toxicology profile of BAM can be found in “Fluopicolide and its Metabolite, 2,6-Dichlorobenzamide (BAM). Amended Human Health Risk Assessment to Support New Section 3 Uses on Brassica Leafy Greens Subgroup 5B, Potatoes, Sugar Beets, Carrots and to Allow Rotation to Wheat,” dated November 21, 2007 (“2007 BAM Risk Assessment”) in docket ID number EPA-HQ-OPP-2006-0481).

Specific information on the studies received and the nature of the adverse effects caused by fluopicolide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Fluopicolide. Human Health Risk Assessment of the new section 3 tolerance on Rotational Corn” in docket ID number EPA-HQ-OPP-2012-0941.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for

derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fluopicolide and BAM used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 20, 2011 (76 FR 22045) (FRL-8859-9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluopicolide, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopicolide tolerances in 40 CFR 180.627. EPA did not consider additional exposures from BAM since the proposed change in use pattern does not add significantly to the BAM dietary exposure, and residues of BAM due to fluopicolide applications are significantly lower than those from dichlobenil applications. EPA is relying on conclusions from the 2007 BAM Risk Assessment. These conclusions remain unchanged

and a revised quantitative BAM risk assessment was not conducted to support the proposed tolerances. EPA assessed dietary exposures from fluopicolide in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fluopicolide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

Acute effects were identified for BAM, and a conservative acute dietary exposure assessment for BAM was conducted. Maximum residues of BAM from fluopicolide field trials on tuberous and corm vegetables, leafy vegetables (except brassica), fruiting vegetables, cucurbit vegetables, grapes (domestic and imported), (except potato), and from dichlobenil field trials on food commodities with established/pending tolerances (40 CFR 180.231) were included in the assessments. The assessments used 100 percent crop treated (PCT) except for apples, blueberries, cherries, cranberries, peaches, pears, and raspberries.

ii. *Chronic exposure.* A chronic aggregate dietary (food and drinking water) exposure and risk assessment was conducted for fluopicolide using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues.

A conservative chronic dietary exposure assessment for BAM was conducted as described in Unit III.C.1.i. for the acute assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopicolide does not pose a cancer risk to humans. Therefore, a quantitative dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

The carcinogenic potential of BAM has been evaluated in only one species, the rat. That study showed an increased incidence of hepatocellular adenomas in high-dose females that was marginally statistically significant. In its previous BAM assessment, EPA assumed that BAM's potential for carcinogenicity is similar to the parent having the greatest carcinogenic potential, specifically, dichlobenil, which has been classified as "Group C, possible human carcinogen" and for which EPA used a reference dose (RfD) approach for quantification of human cancer risk. Accordingly, EPA has assessed BAM's cancer risk by using an RfD approach. For this assessment, EPA relied on BAM chronic exposure assessment as described in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluopicolide. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

EPA used anticipated residues and PCT information for the acute and chronic dietary risk assessments for BAM. For further analysis and EPA's findings under section 408(b)(2)(E) of the FFDCA, see Unit III.C.1.iv. of the preamble to the fluopicolide final rule published in the **Federal Register** of April 20, 2011 (76 FR 22045, 22050) (FRL-8859-9).

2. *Dietary exposure from drinking water.* A new drinking water assessment was not necessary for the establishment of tolerances resulting from inadvertent residues of fluopicolide on rotational corn. Previously, the Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluopicolide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopicolide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the surface water concentrations estimated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS); and Screening Concentrations in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of fluopicolide for chronic exposures (non-cancer) assessments are estimated to be 24.14 ppb for surface water and 0.5 ppb for ground water. Acute and cancer dietary risks were not quantified, as previously discussed.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 24.14 ppb was used to assess the contribution to drinking water.

Considering residues of BAM in drinking water from uses of dichlobenil and fluopicolide, the uses on dichlobenil will result in the highest residues in drinking water. Therefore, the results from dichlobenil (from the use of nutsedge at 10 lb dichlobenil active ingredient/Acre (ai)/(A)) were used in the 2007 BAM Risk Assessment, *i.e.*, 56.2 ppb was used as the value of BAM residues in drinking water in the dietary assessment for both the acute and chronic assessment.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Fluopicolide is currently registered for the following uses that could result in short-term residential exposures: Residential turf grass, recreational sites and ornamental plants. EPA assessed residential exposure using the following assumptions: Residential handlers may receive short-term dermal and inhalation exposure to fluopicolide when mixing, loading, and applying the formulations. Residential post-application exposure via the dermal route is likely for adults and children entering treated lawns or treated gardens and during mowing and golfing activities. Children may also experience exposure via incidental non-dietary ingestion (*i.e.*, hand-to-mouth, object-to-mouth (turfgrass), and soil ingestion) during post-application activities on treated turf. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

BAM is a metabolite/degradate which forms slowly; therefore, the scenarios were assessed in the previous assessment assuming that BAM is present at levels which reflect high end measurements observed in the longer-term metabolism studies in order to provide a protective assessment. The short-/intermediate-term dermal MOEs for adults and children are 10,000 and 6,000, respectively, and the combined incidental oral MOE for toddlers is 62,000. These MOEs are greater than the LOC of 100 for dermal exposure and 1,000 for incidental oral exposure, on the day of application, and therefore, are not of concern. See 2007 BAM Risk Assessment.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluopicolide and any other substances. Although fluopicolide shares a common metabolite, BAM, with dichlobenil, quantification of risks for residues of BAM resulting from fluopicolide was not done as part of this assessment because they contribute an insignificant amount to the total BAM exposure. Furthermore, aggregate risks to BAM are not of concern. For the purposes of this tolerance action, EPA has not assumed that fluopicolide has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at:

<http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database

on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* For fluopicolide, there is no evidence of quantitative susceptibility following *in utero* and/or postnatal exposure in the rabbit and rat developmental toxicity studies or in the 2-generation rat reproduction study. Qualitative susceptibility was observed in the rat developmental toxicity study. Fetal effects (reduced growth and skeletal defects) and late-term abortions were observed at doses at which only decreased body weight gain were observed in maternal animals. There is low concern for this qualitative susceptibility, because the fetal effects and late-term abortions have been well characterized and only occurred at a dose level near the limit dose. Protection of the maternal effects also protects for any effects that may occur during development. There are no residual uncertainties concerning prenatal and postnatal toxicity for fluopicolide.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for fluopicolide is complete.
- ii. There is no indication that fluopicolide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. As discussed in Unit III.D.2. in this document, the degree of concern for the prenatal and/or postnatal toxicity is low; thus, there is no need for the 10X FQPA safety factor to account for potential prenatal or post-natal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopicolide in drinking water. Although EPA has required additional data on transferable residues from treated turf for fluopicolide, EPA is confident that it has not underestimated turf exposure due to the conservativeness of the default turf transfer value and conservative assumptions in the short-term turf assessment procedures (e.g., assuming residues do not degrade over the thirty day assessment period and assuming high-end activities on turf for every day of the assessment period).

For reasons explained in III.D. of the preamble to the fluopicolide final rule published in the **Federal Register** of April 20, 2011 (76 FR 22045) (FRL-8859-9), EPA reduced the FQPA safety factor for BAM to 1X for inhalation and dermal exposure scenarios and retained the 10X FQPA safety factor for all other BAM exposure scenarios. EPA is relying on the findings in the preamble of the April 20, 2011 final rule and the 2007 BAM Risk Assessment for the BAM FQPA safety factor determinations for this action.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD

(cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluopicolide is not expected to pose an acute risk.

The acute dietary exposure estimates for BAM at the 99.9th percentile of the exposure distribution are 11% of the aPAD for the general U.S. population and 28% aPAD for all infants 1 year old, the most highly exposed group.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopicolide from food and water will utilize 12% of the cPAD for children 1-2 years of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopicolide is not expected.

The chronic dietary exposure estimates for BAM are 29% of the chronic cPAD for the general U.S. population and 93% cPAD for all infants (< 1 year old), the most highly exposed group, which is not of concern to the Agency.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluopicolide is currently registered for uses that could result

in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluopicolide.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 110 for adult males and females and 183 for children 6-11 years of age. Because EPA's level of concern for fluopicolide is a MOE of 100 or below, these MOEs are not of concern.

Short-term exposures for fluopicolide's metabolite BAM, may occur as a result of activities on treated turf. Incidental oral exposures related to turf activities have been combined with chronic dietary exposure estimates to assess short-term aggregate exposure for BAM. Since aggregate MOEs for BAM are greater than the LOC, they represent risk estimates that are below the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

5. *Aggregate cancer risk for U.S. population.* As noted in Unit III.A., EPA has determined that fluopicolide is "not likely to be carcinogenic to humans." As discussed in Unit III.C., EPA assessed the BAM cancer risk using an RfD approach. Relying on the BAM chronic risk assessment, EPA determines that BAM does not pose a cancer risk. Therefore, fluopicolide is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluopicolide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for fluopicolide on corn, field, forage; corn, field, grain or corn, field, stover.

C. Revisions to Petitioned-For Tolerances

The established tolerance levels for field corn forage and field corn stover differ from the petition. The petitioner's calculations were based on the sum of fluopicolide and BAM. Since the tolerance expression includes monitoring of residues of fluopicolide only for rotational crops for both food and feed commodities, it is not appropriate to consider residues of BAM in tolerance calculations. Therefore, EPA is establishing tolerances based on field trial data for fluopicolide only and using the Organization of Economic Cooperation and Development (OECD) calculation procedure.

V. Conclusion

Therefore, tolerances are established for residues of fluopicolide, 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]-benzamide, in or on corn, field, forage at 0.08 ppm; corn, field, grain at 0.01 ppm; and corn, field, stover at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction

Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 26, 2014.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.627, in paragraph (d), add alphabetically the following commodities to the table to read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

* * * * *

(d) * * *

Commodity	Parts per million
Corn, field, forage	0.08
Corn, field, grain	0.01
Corn, field, stover	0.20
* * * * *	